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HOUSE BILL 2035
By Rhinehart

AN ACT to amend Tennessee Code Annotated, Section 4-29-220 and Title 63, Chapter 10, to enact the “Tennessee Pharmacy Practice Act of 1996”.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, is amended by deleting Parts 1 and 2 in their entirety and by substituting instead Sections 2 through 19 of this act.

SECTION 2. The practice of pharmacy within the state of Tennessee is declared to be a professional practice affecting public health, safety and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this act, merit and receive the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy.

SECTION 3. The purpose of this act is to define and regulate the practice of pharmacy to protect the health, safety and welfare of the people of Tennessee.

The persons engaged in the practice of pharmacy shall be pharmacists, duly recognized by the state of Tennessee as primary health care providers, and shall be entrusted through this act with a provision of care intended to enhance patients' wellness, prevent illness and optimize outcomes. This act shall be liberally construed to carry out these objectives and purposes.

SECTION 4. As used in this act unless context otherwise requires:

(1) "Administer" is the direct application of a drug to a patient or research subject by injection, inhalation, ingestion, topical application or by any other means.

(2) "Board" is the Tennessee Board of Pharmacy.

(3) "Certification" is a voluntary process by which a practitioner's training, experience and knowledge is identified as meeting or surpassing a standard, defined or approved by the board beyond that required for licensure.

(4) "Collaborative Care Agreement" is a written agreement between prescriber(s) and pharmacist(s) for cooperative management of patients' drug and device-related health care needs, which may include, but need not be limited to, performance of physical assessments; ordering of clinical tests; initiating, modifying, continuing or discontinuing drug or device therapy; and therapeutic drug monitoring with appropriate modification to dose, dosage regimen, dosage forms, or route of administration.

(5) "Compounding" is the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(a) as the result of a prescription order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice;

(b) in anticipation of prescription orders based on routine, regularly observed prescribing patterns; or

(c) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing.

(6) "Continuing Education" means planned, organized learning experiences and activities beyond the basic educational or preparatory program. These learning experiences and activities are designed to promote the continuous development of skills, attitudes, and knowledge necessary to maintain proficiency, provide quality service or products, be responsive to needs, and keep abreast of significant change. (7) "Controlled substance" is a drug, substance or immediate precursor identified, defined or listed in Title 39, Chapter 17, Part 4, and Title 53, Chapter 11.

(8) "Device" is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component part or accessory, that is required under federal or state law to be ordered or prescribed by a person duly authorized.

(9) “Deliver" or "delivery" is the actual, constructive or attempted transfer from one person to another whether or not there is an agency relationship.

(10) "Dietary supplement" is a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following ingredients: a vitamin, mineral, herb or other botanical, amino acid, dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combination of any of these ingredients, and any other products designated as dietary supplements by federal or state law.

(11) "Director" is the Director of the Tennessee Board of Pharmacy.

(12) "Dispense" is preparing, packaging, compounding, or labeling for delivery, and actual delivery of, a prescription drug, non-prescription drug or device in the course of professional practice to a patient or the patient's agent by or pursuant to the lawful order of a prescriber.

(13) "Distribute" is the delivery of a drug or device, other than by administering or dispensing, to persons other than the patient or the patient's agent.

(14) "Doctor of Pharmacy" is a person duly licensed by the board to engage in the practice of pharmacy. "Doctor of Pharmacy" and "pharmacist" shall be used interchangeably within this act and any other provision of Tennessee Code Annotated, and in any rule or regulation promulgated by the state of Tennessee and its agencies.

(15) "Drug" is any of the following:

(a) articles recognized as drugs or drug products in any official compendium or supplement thereto;

(b) articles, other than food, intended to affect the structure or function of the body of man or other animals;

(c) articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or

(d) articles intended for use as a component of any articles specified in this subsection.

(16) "Licensure" is the process by which an agency of government grants permission to an individual to engage in a given occupation upon finding that the applicant has attained the minimal degree of competency necessary to ensure that the public health, safety and welfare will be reasonably protected.

(17) "Label" is any written, printed or graphic matter on the immediate container of a drug or device.

(18) "Labeling" is the process of affixing all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(19) "Manufacturer" is any person, except a pharmacist compounding in the normal course of professional practice, engaged in the commercial production, preparation, propagation, conversion or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container and the promotion and marketing of such drugs or devices.

(20) "Medical order" is a lawful order of a prescriber for a specific patient, that may or may not include a prescription order.

(21) "Non-prescription drug" is a drug that may be sold or dispensed without a prescription and that is labeled and packaged in compliance with applicable state or

federal law. In order to comply with federal and state laws requiring pharmacies to maintain patient profiles with a comprehensive list of medications and devices, pharmacists are authorized to execute prescription orders for non-prescription drugs.

(22) "Non-prescription device" is a device that may be sold or dispensed without a prescription order and that is labeled and packaged in compliance with applicable state or federal law. In order to comply with federal and state laws requiring pharmacies to maintain patient profiles with a comprehensive list of medications and devices, pharmacists are authorized to execute prescription orders for non-prescription devices.

(23) "Patient education" is the communication of information to the patient or caregiver by the pharmacist.

(24) "Patient profile" is a written or electronic record of individual patient information, including, but not limited to, demographic information, medical history, medication and devices utilized, testing results and pharmacist comments.

(25) "Person" means any individual, partnership, association, corporation, and the state of Tennessee, its departments, agencies, and employees, and the political subdivisions of Tennessee and their departments, agencies, and employees, except the department of health and local health departments.

(26) "Pharmacist" is an individual health care provider licensed by the state of Tennessee, pursuant to this act, to practice the profession of pharmacy.

(27) "Pharmacist-in-charge" is the supervisory pharmacist who has the authority and responsibility for compliance with laws and rules pertaining to the practice of pharmacy at the practice site of the pharmacist-in-charge.

(28) "Pharmacy" is a location licensed by this state where drugs are compounded or dispensed under the supervision of a pharmacist, as defined in the rules of the board, and where prescription orders are received or processed.

(29) "Pharmacy intern" is an individual enrolled in or a graduate of a recognized school or college of pharmacy under rules established by the board who is serving a period of time of practical experience under the supervision of a pharmacist, as defined in the rules of the board.

(30) "Pharmacy technician" is an individual who is specifically trained and designated to assist pharmacists in the practice of pharmacy.

(31) "Practice of pharmacy" is a patient-oriented health service profession in which pharmacists interact and consult with patients and other health care professionals to enhance patients' wellness, prevent illness and optimize outcomes. The practice may involve, but is not limited to, interpretation, evaluation, and implementation of medical orders and prescription orders; compounding and dispensing of prescription orders, including radioactive substances; participation in drug, dietary supplement, and health-related device selection, distribution, and administration; drug evaluation and drug utilization reviews; maintenance of patient profiles; and provision of those professional acts, decisions and services, as defined in board rules and regulations, necessary to maintain and manage patient care.

(32) "Prescriber" is an individual authorized by law to prescribe drugs.

(33) "Prescription order" is an order from a prescriber for drugs, devices or treatment for a human or animal, including orders issued through collaborative care agreements.

(34) "Prescription drug" is a drug which under federal law is required to be labeled with either of the following statements: (1) "Caution: Federal law prohibits dispensing without a prescription"; (2) "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian"; or a drug which is required by any applicable federal or state law or regulation to be dispensed only pursuant to a prescription order or is restricted to use by prescribers.

(35) "Provider" or "primary health care provider" includes a pharmacist who provides health care services within the scope of pharmacy practice.

(36) "Unprofessional conduct" is the conduct of a pharmacist, pharmacy intern, or pharmacy technician that is detrimental to patients or to the profession of pharmacy.

(37) "Wholesaler" is a person whose principal business is buying or otherwise acquiring drugs or devices for resale or distribution to persons other than consumers.

SECTION 5.

(a) Any drug dispensed by the Department of Health and Environment or a local health department in traditional services, including, but not limited to, family planning, maternal and child health, tuberculosis and venereal disease must be approved by the board.

Such approval shall be in the form of duly promulgated rules pursuant to the Tennessee Uniform Administrative Procedures Act, compiled in Title 4, Chapter 5.

(b) Where a local health department does not employ a pharmacist, inventory controls, accountability, repackaging, security, storage and distribution of such drugs shall be under the supervision of a pharmacist at the regional level, as defined by the Department of Health and Environment.

SECTION 6. Any insulin preparation shall be dispensed only by or under the supervision of a pharmacist. All insulin preparations must be properly stored in an area not accessible to the general public.

SECTION 7. Notwithstanding any provision of law to the contrary, a pharmacist may, in good faith, dispense to a patient without proper authorization the number of dosages necessary to allow such patient to secure such authorization from such patient's prescriber not to exceed a seventy-two (72) hour supply, if:

(1) The patient offers satisfactory evidence to the pharmacist that the prescriber has placed the patient on a maintenance medication, and that such patient is without valid refills, or for some valid reason cannot obtain proper authorization; and

(2) In the judgment of the pharmacist, the health, safety and welfare of the patient would otherwise be endangered.

This section shall not be construed to authorize dispensing of controlled substance medication without proper authorization.

SECTION 8. There shall exist and be maintained within this state a board of pharmacy. The board shall consist of seven (7) members, one of whom shall be a consumer, who shall enforce this act and all laws that pertain to the practice of pharmacy and shall cooperate with other state and federal governmental agencies regarding any violations of any pharmacy drug or drug-related laws. The board shall have all of the duties, powers, responsibilities, and authority specifically granted or necessary to the enforcement of this act, as well as other duties, powers, responsibilities, and authority that may be granted by law.

SECTION 9.

(a) The governor shall appoint the members of the board, and shall make appointments so that the pharmacist members of the board shall be graduates of a recognized school or college of pharmacy. In making appointments to the board, the governor shall strive to ensure that at least one (1) person serving on the board is sixty (60) years of age or older and that one (1) person serving on the board is a member of a racial minority.

(b) No pharmacist shall be eligible for appointment to the board unless such person has been a pharmacist under this or some other law of this state for a period of at least five (5) years, and during the terms of such person's incumbency shall be actively engaged in the practice of pharmacy.

(c) No consumer shall be eligible for appointment to the board to represent the public at large unless such person has been a resident of Tennessee for at least five (5) years, currently resides in Tennessee, and is a non-health care professional by education. The consumer member shall not own, or have any financial or other interest in, any health care facility or business.

(d) The term of appointment shall be for six (6) years, or until their successors have qualified, and no member of the board is eligible for reappointment.

(e) The Tennessee Pharmacists Association shall annually recommend five (5) duly qualified persons for each vacancy from whom the governor shall be requested to make appointments. Appointees shall, within ten (10) days after appointment, make oath or affirmation to be filed with the secretary of state that they will faithfully and impartially perform their duties.

(f) Members guilty of misconduct may be removed by the governor upon the recommendation of the remaining members. All vacancies occurring other than by expiration of terms shall be filled as to unexpired terms by the governor from the most recent list of nominees of the Tennessee Pharmacists Association.

SECTION 10.

(a) The board shall have a president and a vice-president, who shall be elected annually from its pharmacist members, and a director, who shall be elected by vote of the members of the board. The director shall have been a pharmacist under this or some other law of this state for a period of at least five (5) years, and the director's office shall be maintained at Nashville.

(b) The director shall receive a salary, which shall be fixed by the board, together with proper expenses.

(c) The director is hereby granted authority to administer oaths or affirmations to the same extent as a notary public of the state of Tennessee when acting in connection

with the issuance of licenses and other matters pertaining to the enforcement of the pharmacy and drug laws of this state.

SECTION 11.

(a) It is the duty of the board, through its officers or employees appointed by it or under its supervision for that purpose, to enforce all the laws of the state now or hereinafter enacted which pertain to the practice of pharmacy, the manufacture, distribution, or sale of drugs, and the medication use process including: compounding, selection, preparation/production, dispensing/distribution, patient administration, education, and monitoring of drugs, devices, chemicals or poisons.

(b) The board shall adopt, amend, and repeal rules for the proper administration and enforcement of this act, consistent with this act. The rules shall be adopted, amended, or repealed in accordance with the Tennessee Uniform Administrative Procedures Act, compiled in Title 4, Chapter 5.

The board shall adopt rules establishing minimum standards and conditions for operation of a pharmacy.

If the board determines it necessary in order to protect the health and welfare of the citizens of this state, it may adopt rules concerning the practice of pharmacy in this state also applicable to the practice of pharmacy located in another state.

(c) The board also has the power and authority to adopt, amend and repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession of pharmacy.

(d) The board shall meet at least annually, and at such other times and places as in its judgment are proper, and shall have authority to employ such personnel necessary for the proper conduct of its duties, and shall have the power and authority to appoint pharmacist-investigators whose duties shall be to locate and prosecute violations of any laws or regulations relating to the practice of pharmacy.

(e) The board shall keep a record of all its proceedings. The board shall issue and maintain a register of all persons to whom licenses have been issued and all renewals, and a register of pharmacists having been designated as a pharmacist-in-charge. The board may maintain a register of pharmacy technicians as necessary to maintain public welfare.

(f) The board or its authorized representatives may conduct investigations, gather evidence, and hold hearings concerning alleged violations of this act or of the rules of the board.

The director is granted authority to issue subpoenas for witnesses and records, and to administer oaths to witnesses.

The board has the authority upon a proper showing and for good cause to reinstate any license or certificates revoked by it.

The board is authorized to petition any circuit or chancery court, having jurisdiction of any person who is practicing pharmacy in Tennessee without a valid license or who has violated any of the provisions of this act or the rules of the board, to enjoin such person from continuing to practice within this state.

(g) The board may join professional organizations and associations organized to promote the improvement of the standards of the practice of pharmacy for the protection of the health and welfare of the public.

The board and its director, in order to be informed and to determine the status of boards of pharmacy of the other states desiring reciprocal exchange and in order to be advised regarding the progress of pharmacy throughout the country, may meet with representatives of other boards of pharmacy, at the expense of the board. The board and its director may, in their discretion, attend appropriate professional meetings at the expense of the board.

(h) A majority of the board constitutes a quorum.

(i) The board has the other duties, powers, and authority necessary to enforce this act.

(j) The board shall adopt rules establishing minimum standards and conditions for receiving, preparing, maintaining, transferring and dispensing of prescription orders.

SECTION 12. Any violation of this act, unless otherwise specified by law, shall be classified as a Class C misdemeanor.

SECTION 13. The board is vested with the power and authority to place on probation, suspend, revoke, or refuse to issue or renew any license or registration and, in addition, may impose a civil penalty as defined in the rules of the board, upon a finding that the holder of such:

(1) Has been convicted of a crime;

(2) Has been convicted of violating any of the laws of this state or of the United States relating to drugs or to the practice of pharmacy;

(3) Has been addicted to the use of alcohol, narcotics or other drugs;

(4) Has engaged in conduct prohibited or made unlawful by any of the provisions of this act, or any other laws of the state or of the United States relating to drugs or to the practice of pharmacy;

(5) Has exhibited an incapacity of a nature that prevents a pharmacist from engaging in the practice of pharmacy with reasonable skill, confidence and safety to the public;

(6) Has been guilty of dishonorable, immoral, unethical or unprofessional conduct;

(7) Has had his license to practice pharmacy suspended or revoked by another state for disciplinary reasons; or

(8) Has failed to comply with a lawful order of the board.

SECTION 14.

(a) Except as otherwise provided in this act, it shall be unlawful for any individual to engage in the practice of pharmacy unless currently licensed, or otherwise authorized under this act, to practice under any facet of the provisions of this act.

(b) The board shall be vested with the authority to define the experience and educational requirements requisite for examination for licensure.

(c) The board shall administer the licensure examination and certify all persons in the practice of pharmacy who meet the necessary qualifications required by the board and who make application for licensure.

The board shall promulgate rules and regulations which establish the average grade necessary to pass licensure examinations.

(d) All applicants for examination as pharmacists coming before the board must be graduates of a recognized school or college of pharmacy under rules established by the board and shall be examined in subjects as determined by the board. Applicants must be at least twenty-one (21) years of age.

(e) When satisfied that the qualifications of pharmacists licensed in other states are equivalent to or greater than requirements for licensure in this state, the board may grant licenses to reciprocal applicants from other states. The board may refuse to issue licenses to reciprocal applicants from other states on such grounds as the board may establish in its regulations.

(f) The board shall have the authority to license and register pharmacists, pharmacies, wholesalers, distributors, pharmacy technicians, manufacturers and such other persons as the board may be required to license under federal or state law upon requirements established by regulations of the board. This subsection shall not be construed to include manufacturer's representatives.

(g) The board shall have the authority to renew licenses and registrations and to establish criteria for renewals of licenses and registrations.

SECTION 15. The pharmacist members of the board or their designated agents have the power and authority to regulate the practice of pharmacy and to inspect any site or professional practice, other than storage sites utilized by manufacturer's representatives, where drugs, medicines, chemicals, pharmaceuticals or poisons are manufactured, stored, sold, dispensed, distributed or administered.

All persons with the power to inspect such sites or professional practices shall be pharmacists meeting the requirements established by the board. The provisions of this subsection shall not apply to any person who was an inspector for the board on or before November 1, 1994.

SECTION 16.

(a) The board, by rule, shall establish reasonable and necessary fees so that the fees, in the aggregate, produce sufficient revenue to cover the cost of administering this act.

All fees derived from the operation of this act shall be paid to the board, and shall be used by it for the purpose of defraying the necessary expenses of the board, as determined by its director, in the administration of this act, as provided for in Section 56-1-310.

(b) All civil penalties derived from the operation of this act shall be paid into the general fund.

SECTION 17. The provisions of the Tennessee Uniform Administrative Procedures Act, compiled in Title 4, Chapter 5, shall govern all matters and procedures respecting the hearing and judicial review of any contested case, as defined therein, arising under this act.

SECTION 18. The existing members of the state board of pharmacy shall continue to serve as members of the Tennessee board of pharmacy until their terms expire. All rules and

regulations of the state board of pharmacy shall remain in force and effect until modified, superceded, or repealed by the Tennessee board of pharmacy.

SECTION 19. This act shall be known and may be cited as the “Tennessee Pharmacy Practice Act of 1996”.

SECTION 20. Tennessee Code Annotated, Section 4-29-220, is amended by deleting subdivision (32) in its entirety and by substituting instead the following:

( ) Tennessee board of pharmacy created by Section 8 of this act.

SECTION 21. This act shall take effect on January 1, 1997, the public welfare requiring it.